**REMARKS**

The Office Action and the cited and applied reference has been carefully reviewed. No claim is allowed. Claims 1 and 4 presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

Claims 1, 2, and 4 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection is obviated by the amendment to the claims.

Claims 1, 2, and 4 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is respectfully traversed.

1) The examiner states that the disclosure fails to provide a convincing correlation between measurement of the level of anti-Tat antibodies or anti-Tat antibodies and p24 antigen and the stage of disease progression. The examiner holds that the data set forth in Table 2, page 13 of the specification suggests that the vast majority (~73%) of progressors actually display low anti-Tat antibody levels, thereby reinforcing the concept that the correlation is quite weak.

In Example 1 of the present specification there are 2 main populations, NP and FP. The NP population is itself divided in 2 sub populations NP-NP and NP-P.

-The NP-NP population are subjects initially enrolled as non progressor (infected for more than 8 years with CD4 cell counts above 500) and who remain stable during the 2 years follow-up after their inclusion.

-The NP-P population are subjects initially enrolled as non progressor (infected for more than 8 years with CD4 cell counts above 500) and who exhibit signs of progression during the 2 years follow-up after their inclusion.

-The FP patients are patients who have declined towards very low CD4 cell counts less than 3 years after their seroconversion.

Basically NP patients (NP-NP and NP-P) have not reached the AIDS stage, while all FP patients have AIDS.

The presently claimed method discriminates between stable patients like NP-NPs versus patients progressing towards AIDS (NP-Ps). All these patients have not yet reached the AIDS stage where the level of anti-Tat antibodies is low. As mentioned by the examiner, the mean level of anti-Tat Abs in Table 1, page 11 of the present specification is 0.39 among all NPs and 0.32 in FPs. The NP-Ps have decreased levels of anti-Tat Abs compared to NP-NPs and they make the average level of anti-

Tat Abs lower among NPs. As stated by the examiner, Table 2 does indeed show that the vast majority (~73%) of NP-P display low anti-Tat antibody levels. The presently amended claims make clear that the low anti-Tat antibody levels (below the mean) distinguishes NP-P from NP-NP with high antibody levels (above the mean). The presently claimed method therefore discriminates between the progressing patients such as NP-Ps (not yet at the AIDS stage) versus non progressive patients such as NP-NPs who have higher anti-Tat Abs.

2) The examiner asserts that the prior art teaches that Tat antibody profiles are not predictive of clinical outcome in HIV-infected patients.

However, as argued in the response filed January 16, 2004, applicants re-emphasize that the examiner is only citing references in which the anti-Tat antibody levels are examined in AIDS patients. These patients at such an advanced stage of disease have very little remaining anti-Tat antibodies. It would be clear that the presently claimed method does not predict disease prognosis in these patients and is not intended to. The reason why the prior art did not observe the prognostic value of anti-Tat antibody levels is that they worked with only AIDS patients, whereas the presently claimed method distinguishes between stabilized patients (NP-NP) and those who will have disease progression (NP-P).

3) The examiner further asserts that the prior art teaches that p24 antigen levels are also not predictive of clinical outcome in HIV-infected patients and that the skilled artisan would readily question the usefulness of p24 antigen measurements as a predictor of disease progression.

For the same reasons discussed in 2) above, i.e., only examining patients in the advanced (AIDS) stage of disease, the references cited by the examiner did not discover the correlations in the method according to the present invention. Moreover, with regard to the examiner's comment in the paragraph bridging pages 4 and 5 of the Office Action, the examiner is quite correct that nearly 75% of the NP-P progressor population actually display low levels of anti-Tat antibodies. It is also true that NP subjects who exhibit higher levels of anti-Tat antibodies are most often NP-NPs. Accordingly, those of skill in the art can indeed use the presently claimed method to distinguish between NP-NPs and NP-Ps based on whether the anti-Tat antibody levels and p24 antigen levels are above or below the mean value, as presently recited in the amended claims.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claim 5 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Rodman et al. (1992). While applicants do not concede to the examiner's position, for the purposes of

business strategy to advance prosecution and without prejudice to refilling in a continuation application, this rejection is made moot by the cancellation of rejected claim 5.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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